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09/016 061

APPLICATION NUMBER	FILING DATE	FIRST NAMED APPLICANT	ATTY. DOCKET NO.
09/016,061	01/30/98	HUSE	W P-1X2965
CATHRYN CAMPBELL CAMPBELL & FLORES SUITE 700 4370 LA JOLLA VILLAGE DRIVE SAN DIEGO CA 92122			EXAMINER
HM22/1124			PAPER NUMBER
1644			DATE MAILED: 11/24/99

This is a communication from the examiner in charge of your application.  
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#### OFFICE ACTION SUMMARY

☒ Responsive to communication(s) filed on 9/13/99

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 D.C. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 1 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

#### Disposition of Claims

- ☒ Claim(s) 56-104 is/are pending in the application.  
Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- ☒ Claim(s) 56-104 are subject to restriction or election requirement.

#### Application Papers

- ☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
- ☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.
- ☐ The proposed drawing correction, filed on \_\_\_\_\_ is ☐ approved ☐ disapproved
- ☐ The specification is objected to by the Examiner.
- ☐ The oath or declaration is objected to by the Examiner.

#### Priority under 35 U.S.C. § 119

- ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- ☐ All ☐ Some\* ☐ None of the CERTIFIED copies of the priority documents have been
- ☐ received.
- ☐ received in Application No. (Series Code/Serial Number) \_\_\_\_\_
- ☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\*Certified copies not received: \_\_\_\_\_

- ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e).

#### Attachment(s)

- ☐ Notice of Reference Cited, PTO-892
- ☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). \_\_\_\_\_
- ☐ Interview Summary, PTO-413
- ☐ Notice of Draftsperson's Patent Drawing Review, PTO-948
- ☐ Notice of Informal Patent Application, PTO-152

-SEE OFFICE ACTION ON THE FOLLOWING PAGES-

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### DETAILED ACTION

1. Applicant's amendment, filed 9/13/99 (Paper No. 10), is acknowledged.  
Claims 1-55 have been canceled.  
Claims 80-104 have been added.

Claims 56-104 are pending.

2. **Please Note:** In an effort to enhance communication with our customers and reduce processing time, Group 1640 is running a Fax Response Pilot for Written Restriction Requirements. A dedicated Fax machine is in place to receive your responses. The Fax number is 703-305-3704. A Fax cover sheet is attached to this Office Action for your convenience. We encourage your participation in this Pilot program. If you have any questions or suggestions please contact Paula Hutzell, Ph.D., Supervisory Patent Examiner at Paula.Hutzell@uspto.gov or 703-308-4310. Thank you in advance for allowing us to enhance our customer service. Please limit the use of this dedicated Fax number to responses to Written Restrictions.

3. Restriction to one of the following inventions is required under 35 U.S.C. § 121:

I. Claims 56-97 drawn to  $\alpha_v\beta_3$ -specific antibodies and functional fragments thereof, classified in Class 530, subclass 387.1, 387.3 and Class 536, subclass 23.53.

II. Claims 98-104, drawn to a method of inhibiting a function of  $\alpha_v\beta_3$ , or of treating a  $\alpha_v\beta_3$ -mediated disease with  $\alpha_v\beta_3$ -specific antibodies, classified in Class 424, subclass 130.1, 133.1.

4. Inventions I and II are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (M.P.E.P. § 806.05(h)).

In the instant case, the antibodies as claimed can be used in a materially different process such as various affinity purification procedures or detection assays.

Applicant's election with traverse of Group I in Paper No. 10, as it would apply to current pending claims, is acknowledged. The traversal is on the ground(s) that it would not be an undue burden. This is not found persuasive because the inventions must be independent (see MPEP 802.01, 806.04, 808.01) or distinct as claimed (see MPEP 806.05-806.05(I)) for the reasons of record set forth in the Restriction Requirement (Paper No. 5).

The requirement is still deemed proper and is therefore made FINAL

5. Because these inventions are distinct for the reasons given above and the search required for Group I is not required for Group II and Groups I and II have acquired a separate status in the art as shown by their different classification and divergent subject matter, restriction for examination purposes as indicated is proper.

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6. This application contains claims directed to the following patentably distinct species of the claimed Groups I/II: wherein the  $\alpha_v\beta_3$ -specific antibody or functional fragment is selected from the numerous combination of heavy/light chains, CDR's and amino acid substitutions encompassed by the claims. The sequences differ with respect to their structure to such an extent that a person of ordinary skill in the art would not envision one in view of the other. They are therefore separate and patentably distinct species in view of each other.

Therefore, applicant is required to elect an ultimate  $\alpha_v\beta_3$ -specific antibody species comprising a distinct heavy and light chain and specific CDR's or amino acid substitutions.

Applicant should distinctly point out which ultimate  $\alpha_v\beta_3$ -specific antibody species is being elected, including which specific SEQ ID NOS. read upon said sequence.

Applicant is required under 35 U.S.C. § 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 56, 80 and 98 are generic, for example.

7. Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 C.F.R. § 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. M.P.E.P. § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. § 103 of the other invention.

Applicant is advised that a response to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

8. In the interest of compact prosecution, applicant is invited to point out which  $\alpha_v\beta_3$ -specific antibody species or sequences comprise amino acid substitutions that may be considered free of the prior art.  $\alpha_v\beta_3$ -specific antibodies, including Vitaxin-specific antibodies were known in the prior art. Therefore, chimeric antibodies, CDR-grafted antibodies as well as CDR-grafted antibodies with changes to framework amino acids residues known and used in the prior art would be held anticipated or obvious in view of the prior art. For example, applicant has provided patents in the IDS's, filed 7/15/98 and 8/17/98, drawn to humanizing antibodies of interest. Again, applicant is invited to advance the prosecution of those  $\alpha_v\beta_3$ -specific antibody species or sequences comprise amino acid substitutions that may be considered free of the prior art in view of these considerations.

9. Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed.

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10. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. § 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filed petition under 37 C.F.R. § 1.48(b) and by the fee required under 37 C.F.R. § 1.17(h).

11 Any inquiry concerning this communication or earlier communications from the examiner should be directed to Phillip Gambel whose telephone number is (703) 308-3997. The examiner can normally be reached Monday through Thursday from 7:30 am to 6:00 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (703) 308-3973. Any inquiry of a general nature or relating to the status of this application should be directed to the Technology Center 1600 receptionist whose telephone number is (703) 308-0196.

Papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center telephone number is (703) 305-3014.

Phillip Gambel, PhD.  
Patent Examiner  
Technology Center 1600  
November 22, 1999

*Phillip Gambel*